



Office of Nutritional Products
Labelling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
2nd December 2003



Dear Sir or Madam,

This letter serves as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Boots Retail USA is using the following statements on the label or in the labelling of

Boots Detox 28 Day Introductory Kit

"The Boots Detox product range works in harmony with your body to help flush away impurities and stimulate your body's natural detoxifying systems, leaving you purified and revitalised. The 28 Introductory Kit is a selection of complimentary internal and external treatments to rebalance your system, leaving you cleansed, energised and revitalised."

"the 28 Day Plan targets and helps protect the body's detoxifying organs to help your system expel harmful impurities. Combined with the simple lifestyle and nutritional advice in the enclosed booklet, you are only 28 days away from a cleaner, more energised body."

"Detoxify your digestive system. Purify and revitalise with essential friendly bacteria to help digestion and maintain your immune system."

"These tablets contain an extract which attacks smells where they originate in the body. This helps to reduce body odours that may be associated with the side effects of detoxing."

This kit contains the following dietary supplement products and associated statements;

1. Boots Detox 28 Day Plan Total Optimisation Dietary Supplement

consisting of:-

Boots Detox 28 Day Plan Digestive Support Dietary Supplement (dietary ingredients; Inulin)

and

Boots Detox 28 Day Plan Body Support Dietary Supplement (dietary ingredients; Vitamin C (as Ascorbic Acid), Vitamin E (as D Alpha Tocopherol), Selenium (as Sodium Selenite Pentahydrate), Gamma Linolenic Acid from Evening Primrose Seed Oil, Aloe Vera Leaf Extract.



Carton

"The 28 Day Plan uses ingredients found in nature to work in harmony with your body to optimise your natural ability to detoxify. Toxin build up is gently eliminated by optimising your detoxifying systems. The plan will rebalance, purify and energise your system, leaving you feeling revitalised."

"The 28 Day Plan targets and helps protect the body's detoxifying organs to help your system expel the toxic substances introduced through diet and the environment. Taken in conjunction with simple nutritional guidelines to minimise the introduction of new pollutants, you are only 28 days away from a cleaner, more energised body. You'll never want to return to the way you were."

Pot label (capsules)

"These capsules contain selected ingredients to work in harmony with your body to help detoxify your organs. Gently eliminating impurity build up, leaves you feeling revitalised."

Pot label (tablets)

" - Food for the friendly bacteria helps to optimise the health of your digestive system, helping your body's natural detoxifying action to work more effectively" .

2. Boots Detox Body Freshener Dietary Supplement (dietary ingredients; Agaricus Bisporus extract)

"These tablets contain an extract which attacks smells where they originate within the body. This helps to reduce body odours that may be associated with the side effects of detoxing."

"The Body Freshener tablets contain an extract which helps it neutralise odours in the intestine where they originate, resulting in fresher breath and reduced odours."

3. Boots Detox Digestive Cleanser Vitalising Balancer Dietary Supplement (dietary ingredients: Lactic Acid Bacteria (as Lactobacillus), Bifidobacterium Bifidum).

"Detoxify, purify and revitalise with essential friendly bacteria to help digestion and maintain your immune system."

" The Boots Detox Digestive Cleanser capsules contain 1,000,000,000 'friendly' bacteria that will displace the 'bad' bacteria in your digestive tract. This will help digestion and maintain your immune system."



These statements are accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and

accurate and the company has substantiation that these statements are truthful and not misleading.

Sincerely,

A handwritten signature in cursive script, appearing to read "JBurton", with a horizontal line drawn underneath it.

Jane Burton
International Regulatory Affairs

Boots Retail USA Inc.,
Stamford,
CT 06901.